

EXHIBIT 10
Part 3 of 4

4. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The final rule establishes three compliance requirements that will allow the USPTO to conduct a better and more thorough and reliable examination of patent applications.

- Submittal of an examination support document (ESD) for certain applications;
- Submittal of a petition in support of certain requests for continuing applications or continued examinations;
- Submittal of information related to patentably indistinct claims.

The following subsections discuss these requirements and estimate the associated burden on applicants that must comply with them.

To develop the estimates for the incremental costs resulting from the requirements of the final rule, the analysis uses the following information and data sources:

- Activities resulting in costs were identified based on a review of the draft final rule (provided by the USPTO), the proposed rules, and on discussions with USPTO staff.¹¹
- USPTO fees charged of patent applicants and patent holders were taken from the USPTO's fee schedule.¹²
- The costs associated with baseline patent application preparation were taken from an American Intellectual Property Law Association (AIPLA) report entitled *Report of the Economic Survey 2005*.¹³
- Finally, USPTO staff provided estimated unit costs for a variety of factors, as noted in Appendix A.

All costs are calculated in 2006 dollars. The analysis applies a legal services labor rate of \$233 per hour¹⁴ (a composite of attorney and paralegal wage rates), and conservatively assume the applicant's labor rate is \$150 per hour. The resulting costs are summarized in Section 5.2.

¹¹ *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR 48 (Jan. 3, 2006); *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR 61 (Jan. 3, 2006)

¹² <http://www.uspto.gov/web/offices/ac/qs/ope/fee2007february01.htm>.

¹³ AIPLA. *Report of the Economic Survey 2005*. Arlington, VA. September 2005.

¹⁴ This labor rate is a blended composite wage based on data from the AIPLA report entitled *Report of the Economic Survey 2005*. The analysis updated the 2004 composite wage rate to 2006 dollars based on the Consumer Price Index.

4.1 Examination Support Document

Under the final rule, patent applicants will be required to submit an ESD if the application contains more than five independent claims or more than 25 total claims. The final rule states that the ESD must contain the following six elements (Section 1.261(a)(1)-(6) of the final rule):

- (1) A statement that a preexamination search was conducted, including an identification of the field of search by United States class and subclass and the date of the search, where applicable, and, for database searches, the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search;
- (2) An information disclosure statement in compliance with § 1.98 citing the reference or references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form);
- (3) For each reference cited, an identification of all the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the reference;
- (4) A detailed explanation of how each of the claims (whether in independent or dependent form) is patentable over the references cited with the particularity required by § 1.111(b) and (c);
- (5) A concise statement of the utility of the invention as defined in each of the independent claims; and
- (6) A showing of where each limitation of each of the claims (whether in independent or dependent form) finds support under the first paragraph of 35 U.S.C. 112 in the written description of the specification. If the application claims the benefit of one or more applications under title 35, United States Code, the showing must also include where each limitation of each of the claims finds support under the first paragraph of 35 U.S.C. 112 in each such application in which such support exists.

Patent applicants with applications that exceed the independent or total claims thresholds will incur costs to prepare and submit the ESD.

To estimate the cost of the ESD, the analysis considers each of the six elements in the ESD.

The first element of the ESD requires the applicant to conduct a patent search. Although applicants currently are not required to conduct a patent search, most patent applicants (55 percent) conduct one as part of the application process. According to AIPLA estimates, the cost of a patent search ranges from approximately \$1,000 for a relatively simple patent application up to approximately \$2,500 for a relatively complex patent application.

Under the final rule, applicants that must prepare an ESD will have an incentive to complete the patent search prior to completion of their applications and ESDs. The reason for this is that doing so will reduce their costs for completing other portions of the

ESD (due to the heightened familiarity they will have with the patent search relative to the application). Given this incentive, it would be reasonable to assume that all applicants required to prepare an ESD (including conducting a patent search) would choose to complete the patent search prior to completing their application. Such an assumption would allow the analysis to account for lower ESD preparation costs than apply in cases where the patent search is not conducted until after the application is completed. Nevertheless, as a conservatism, the analysis assumes that only 50 percent of applicants in this situation will conduct the patent search prior to completing the application. The remaining 50 percent of applicants facing ESD requirements are assumed to complete the application first, even though doing so leads to higher ESD preparation costs.

Exhibit 4-1 presents the time estimates for each element of the ESD, assuming the applicant has/hasn't completed the patent search prior to completing the application.

Exhibit 4-1
Examination Support Document Time/Cost Estimates

| ESD Element | Cost Basis | Estimate Assuming Patent Search is Conducted Prior to Application | Estimate Assuming Patent Search is Conducted After Application |
|-------------|------------------------------|---|--|
| Element 1 | Application-based | \$1,000 - \$2,500 | \$1,000 - \$2,500 |
| Element 2 | Application-based | 1 hour | 1 hour |
| Element 3* | First two independent claims | 30 minutes each | 40 minutes each |
| | Remaining independent claims | 10 minutes each | 10 minutes each |
| | First 10 dependent claims | 10 minutes each | 10 minutes each |
| | Remaining dependent claims | 5 minutes each | 5 minutes each |
| Element 4 | Independent claims | 10 minutes each | 15 minutes each |
| | Dependent claims | No additional time needed | No additional time needed |
| Element 5 | Application-based | 30 minutes | 30 minutes |
| Element 6 | First two independent claims | 20 minutes each | 20 minutes each |
| | Remaining independent claims | 10 minutes each | 10 minutes each |
| | Dependent claims | 5 minutes each | 5 minutes each |

* To mitigate the final rule's cost impact on small entities, the USPTO will not require small entities, as defined in 13 CFR 121.802, to complete Element 3 of the ESD.

This analysis assumes that the cost associated with three of the ESD elements is “application-based.” Specifically, for elements 1, 2, and 5 of the ESD, applicants will incur a flat cost. Conversely, the cost incurred by applicants to complete elements 3, 4, and 6 of the ESD will vary depending on the number of independent and dependent claims in an application. To reduce the final rule’s cost impact on small entities, however, the final rule does not require small entities to complete Element 3.

Exhibit 4-2 summarizes the resulting estimates of incremental ESD costs for affected small entities.

- Assuming a patent search is conducted before the patent application is completed, this analysis estimates that the incremental cost associated with the ESD ranges from \$2,563 to \$10,136.
- Assuming a patent search is conducted after the patent application is completed, this analysis estimates that the incremental cost associated with the ESD ranges from \$5,170 to \$13,121.

Exhibit 4-2
Summary of Small Entity Incremental Costs Associated with the ESD

| | Incremental Cost |
|---|-------------------|
| For applicants that already conduct a patent search in the baseline | \$2,563-\$10,136* |
| For applicants that do not conduct a patent search in the baseline | \$5,170-\$13,121* |

* Cost of preparing an Examination Support Document varies depending on the number of claims in the application. Range shown covers up to 50 independent claims or 350 total claims. The analysis does not assume a range of costs per application, but instead applies the specific cost appropriate to the number of claims in each application.

4.2 Petition for Continuing Applications or Continued Examinations

The final rule also sets a reporting requirement related to continued examination filings. According to the final rule, an application or chain of continued examination filings may include no more than two continuing applications (continuation or continuation-in-part applications), and no more than a single request for continued examination in any one of these three applications (the initial or two continuing applications), without a petition showing why the amendment, argument, or evidence presented could not have been previously submitted. Based on a USPTO staff estimate, this analysis estimates that the petition required under the final rule will cost applicants \$1,000 to complete.¹⁵

¹⁵ In the OMB Paperwork Burden Analysis for the proposed continued examination filings rule, the USPTO estimated the cost of the petition to be \$572. As a conservatism, this analysis assumes the cost of the petition will be higher (\$1,000).

4.3 *Information Related to Patentably Indistinct Claims*

The final rule also contains a reporting requirement to address patentably indistinct claims. This requirement applies to applicants with pending applications or patents that (1) have an effective filing date within two months of the filing date of the pending application; and (2) name at least one inventor in common with the pending application. Under the final rule, the applicant must name these other commonly-owned applications or patents and must file a terminal disclaimer or explain how the applications (or application and patent) contain only patentably distinct claims if they have the same effective filing date and contain substantial overlapping disclosure.

The analysis estimates that there will be no costs associated with the indistinct claims portion of the rule. The intention of the provision is to close a loophole that might otherwise open after the ESD provisions are promulgated. That is, to avoid preparing an ESD, an applicant might otherwise be able to divide his or her claims among two simultaneous applications ("parallel prosecution"). The indistinct claims provision would prevent this by forcing applicants to justify the indistinct claims in the applications, submit a terminal disclaimer (the costs of which are associated with existing rules) or, more likely, abandoning one of the applications and adding its claims to the other application. USPTO staff believe it would not be possible to successfully justify the dual applications in this case. The applicant, too, would realize this and therefore would not submit such applications. Thus, given that the final rule would establish these rules in advance, the effect of the indistinct claims provision would be to prevent the dual application scenario from being used as a means of avoiding the ESD requirement.

Applicants currently file dual applications for reasons other than avoiding the prospective ESD requirement. This final rule would not generate incremental costs in this situation because 37 CFR 1.78(b) currently provides that applicants can be required to eliminate patentably indistinct claims from all but one application and the double patenting doctrine requires a terminal disclaimer if the patentably indistinct claims are not eliminated from all but one application.

5. Impacts Assessment

To comply with the Regulatory Flexibility Act, agencies must determine whether proposed actions will have a significant economic impact on a substantial number of small entities. If the action will not have a significant impact on a substantial number of small entities, then the agency may certify that this is the case instead of preparing a regulatory flexibility analysis, as would otherwise be required under the Act.

This section considers whether the costs of the rule will lead to a significant economic impact on a substantial number of small entities. Section 5.1 describes the methodology used in this assessment. Section 5.2 presents the results of the analysis. Finally, Section 5.3 draws conclusions regarding whether certification is appropriate.

5.1 Methodology

To assess whether the costs of the rule will lead to a significant economic impact on a substantial number of small entities, this analysis proceeds in four general steps.

- (1) Select an appropriate indicator for measuring impacts;
- (2) Estimate the incremental compliance costs of the final rule;
- (3) Quantify the impacts and the number of entities impacted; and
- (4) Evaluate the impacts.

Each of these steps is described below.

5.1.1 Selection of Impact Measure

The analysis evaluates impacts based on the ratio of annualized incremental cost as a percent of total revenue. This measure was selected after evaluating the following six candidate measures:

- *Incremental Cost.* This measure considers the increase in cost (present value) to a given entity resulting from the rule. The incremental cost is equivalent to the cost of obtaining a patent under the new rule minus the cost of obtaining a patent under the current rules. While intuitively simple, this measure does not address the significance of the cost relative to any characteristic (e.g., size) of the small entity that incurs the cost. Therefore, *incremental cost* is used in this analysis only as an intermediate result.
- *Annualized Incremental Cost.* This measure calculates what the annual incremental cost of the rule would be if the incremental cost (as described above) were financed and paid off in annual installments. This measure can be useful in situations where it is reasonable to allocate costs over a multi-year period. Spreading costs over time is generally appropriate for capital investments (e.g., equipment) that will contribute to income over an extended period. In the case of patents, for example, it is reasonable to allocate the cost of obtaining a patent over the 20-year life of the resulting patent, because the patent holder retains exclusive rights over the patent during that time. In fact, generally accepted accounting principles (GAAP) for amortizing patents require patents to be amortized over the life of the patent.¹⁶ Nevertheless, this measure by itself does not address the significance of the cost relative to the entity that incurs it. Therefore, *annualized incremental cost* is used in this analysis only as an intermediate result.
- *Percent Increase in Costs.* This measure calculates the incremental cost as a percentage increase relative to the “baseline” costs, which are the costs applicable in the absence of the rule. The *percent increase in costs* can be useful,

¹⁶ See, for example, *Statement of Accounting Standards No. 142, Goodwill and Other Intangible Assets*, Financial Accounting Standards Board, June 2001.

particularly when percentage increases are small. However, this measure does not address the significance of the cost relative to the entity that incurs the cost. For example, even if a rule leads to a 100 percent increase in costs, that increase might not be significant to an entity if the original cost is sufficiently small. In addition, estimating the “baseline” cost of preparing a patent application is difficult due to the difference between applications with respect to the complexity of the invention, the state of prior art, and the skills and experience of the applicant.

- *Cost as a Percent of the Expected Value of the Patent.* This measure considers the incremental cost as a fraction of the expected value of the patent. In theory, this measure should be very useful in evaluating whether impacts are likely to be significant. In practice, however, this approach presents significant challenges. For example, it would not be possible to identify the expected value of individual patent applications, which would be ideal from a theoretical standpoint. Instead, it would be necessary to apply one or more average values and make related assumptions. This study evaluated the literature to find information on the value of patent applications and identified estimates ranging from \$220,000 to \$1.3 million. These finding do not appear sufficiently robust to support use of this measure for the present purposes (see Appendix B for further discussion). Finally, this measure would not recognize other types of value that patents and patent applications can provide to applicants (e.g., by providing enhanced competitive protection to existing business lines).
- *Incremental Cost as a Percent of Revenue, and Annualized Incremental Cost as a Percent of Revenue.* These measures consider cost as a percentage of an entity’s total revenue – a common measure of an entity’s size – and are common screening measures for evaluating whether costs are significant. All else equal, costs that are small relative to a firm’s size are less significant than costs that are larger. Although other factors also influence whether a given cost is significant to an entity, such as the entity’s profitability and its ability to “pass through” costs to its customers, these two ratios both are useful screening measures that are applicable to most types of entities.
- *Incremental Cost as a Percent of Profits.* Incremental cost relative to profits is often considered a useful measure of impacts because profit represents “net” revenue after all expenses have been paid. This measure raises some unique issues, however, including the “adequacy” of any given return on equity, the effect of tax incentives on small entities, and whether a cost should be considered “more significant” to firms that are managed poorly as opposed to firms that are managed more effectively. From a more mechanical perspective, profits data are relatively difficult to obtain, particularly when affected entities span numerous industries, as is the case with patent applicants.

This study focuses on *annualized incremental cost as a percent of revenue* for several reasons: (1) it considers costs on an annualized basis, which is consistent with the

generally accepted recognition that a patent is an asset conveying a multiyear earning potential; (2) it evaluates impacts relative to revenue, which is a useful and relevant measure of the size of an entity; (3) it can be applied readily across many industries and entity types; (4) data availability typically is not an impediment to analysis; and (5) most people understand it without difficulty.

5.1.2 Estimation of Incremental Compliance Costs

The analysis estimates incremental costs resulting from the requirements of the final rule using the information and sources described in Section 4 and Appendix A. These sources include USPTO staff, AIPLA, and the USPTO fee schedules.

The resulting costs are summarized in Section 5.2. The incremental costs are annualized over a period of 20 years (to coincide with the life of the patent) using an interest rate of seven percent.

5.1.3 Quantify Impacts and Number of Entities Impacted

In the next step, the analysis quantifies the impacts of the final rule and the number of entities impacted at the identified thresholds (described in Section 5.1.4). Impacts are based on incremental costs calculated as described in Section 5.1.2. As noted previously, some costs (those associated with the claims requirements) are a function of the number of claims contained in an application. Therefore, the analysis appropriately models different incremental costs and impacts for filings having different numbers of included claims.¹⁷ All estimates of the number or percentage of affected entities and the distribution of applications by number of claims are based on data from PALM for fiscal year 2006.

5.1.4 Evaluate the Rule's Economic Impacts

In the last step, the quantitative results are screened to determine whether the rule is likely to have a significant impact on a substantial number of small entities.

Significant Impact Criteria

To evaluate *significant impact*, the study considers the ratio of *Annualized Incremental Cost as a Percent of Revenue*, as described earlier. Impacts are evaluated relative to two screening thresholds:

- Entities at or above a threshold value of *three percent* are presumed to face significant impacts unless additional analysis of these entities indicates this will

¹⁷ For applications affected only by the claims requirements, PALM provided data on the number of claims for each application. The analysis conservatively assumes that the filings (other than RCEs) affected by both the claims requirements and by the continued examination filing requirements are those non-initial applications shown by the PALM data as having the most claims. For RCEs, the analysis assumes the same distribution by number of claims as PALM shows for non-initial applications.

not be the case. Note that a three percent threshold is equivalent to determining whether an entity has annual revenue of at least 33.3 times the annualized incremental cost.

- Entities at or above a threshold value of *one percent* are presumed to face more moderate impacts that qualify as significant if collectively incurred by a *substantial number* of small entities, as discussed below. Note that a one percent threshold is equivalent to determining whether an entity has annual revenue of at least 100 times the annualized incremental cost.

Because the rule's incremental costs are relatively small, the analysis proceeds by considering how much annual revenue an affected entity – large or small –would have to earn in order to avoid these impacts. To the extent that these minimum levels are below the levels needed to run even the smallest business, then the analysis can conclude that the rule will not result in significant impacts. For purposes of analyzing this rulemaking, the smallest business is modeled as a sole proprietorship owned by a creative and/or technical individual who currently is capable of paying for or financing all necessary patent filing costs and maintenance fees (under current rules) associated with an application of a type that would be affected by the final rule. These filing and maintenance fees can vary by filing, but this study estimates that they range from \$19,940 to \$49,155 for filings that would be affected by the final rule. This study assumes that the minimum annual revenue that would support an individual's living expenses, as well as his/her patent filing and maintenance costs, is \$75,000.¹⁸ Therefore, the smallest business in the analysis would exceed the three percent threshold at annualized incremental costs of \$2,250 or higher, and it would exceed the one percent threshold at annualized incremental costs of \$750 or higher. Businesses that earn higher revenue would exceed these thresholds only at proportionately higher incremental costs.

Note that the above thresholds are intended to serve as screening-level indicators and may be overly sensitive for purposes of identifying economic impacts. For example, to the extent that affected entities may earn higher future revenue due to the commercialization of the patent, impacts based on current revenue levels will be overstated. Additional analysis would be needed to definitively determine whether entities exceeding this threshold are likely to incur significant impacts as a result of the rule.

Substantial Number Criteria

The key objective of this analysis is to determine whether the USPTO's final rule will result in a significant economic impact on a *substantial number* of small entities. The concept of a "substantial number" is necessarily relative, however. For purposes of analyzing this rulemaking, it is reasonable to consider it relative to the total number of

¹⁸ Revenue of \$75,000 is higher than the U.S. median income (which is slightly less than \$50,000), but it seems reasonable in light of the creative/technical abilities of an individual seeking a patent, as well as his/her current ability to fund the development and processing of the patent application (under existing regulations) as well as the required maintenance fees.

small entities that apply for patents. The USPTO's PALM system indicates that, in FY 2006, there were a total of 111,178 patent filings submitted by entities claiming small-entity status.

Most of these small entities, however, will not incur costs under the final rule. Of those that are affected, some might face potentially significant impacts. This analysis assumes that a "substantial number" of small entities exists if the number of entities impacted at a given impact threshold (e.g., three percent of revenue) constitutes at least 20 percent of all small entities that apply for patents. The analysis considered developing a numerical threshold (e.g., 2,500) as another criterion for determining "substantial number," but did not do so for two reasons. First, it was clear that the final rule would not affect enough small entities to exceed any of the numbers that would have been considered. Second, given that the number of patent filings the USPTO receives increases by 7 to 8 percent per year when the economy is good, selection of a number that would be appropriate for this year's rulemaking likely would be inappropriate in the near future.

Assumptions and Uncertainties

The analysis relies on several data sources as documented throughout this report. In addition, two assumptions are worth noting.

First, due to data limitations, the analysis considered patent filings rather than applicants. To the extent that applicants might have more than one application in process at a time, this will tend to underestimate impacts. Although the assumption certainly does not hold true for many large firms, these firms have sufficient revenue to avoid significant impacts under the final rule. The assumption is much more reasonable, however, for the smallest firms, such as the sole proprietorship described above, which might face significant impacts under the rule. See additional discussion in Section 3.2.2.

Second, the analysis of the continued examination filing requirements assumes, as also discussed in Section 3.2.2, that most applicants who would have triggered the final rule's claims requirements based on the applications they submitted in FY 2006 will not trigger those requirements once the rule is promulgated. Instead, these applicants will choose to submit an initial application with fewer claims (to avoid having to prepare an ESD) and then will take advantage of the various steps in USPTO's patent application review process to add additional claims. The final rulemaking contains a description of how these applicants can prosecute their applications in this manner to avoid triggering the ESD requirement.

5.2 Results

The presentation of results is organized in three parts: (1) costs; (2) number of small entities affected by the rule; (3) magnitude of impacts; and (4) unquantified benefits.